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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/739,451	12/17/2003	Dennis Rowe	03762.016200	9345

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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
04/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/739,451	ROWE ET AL.	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 16-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/21/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment and Request for Continued Examination filed on 01/23/209.

Claims 1 and 2 have been amended.

Claim 15 has been cancelled.

Claims 1-14 and 16-18 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/21/2009 has been entered.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 01/21/2009 was noted and the submission is in compliance with the provision of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 1 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear to what extent or percentage of starch is ungelatinized constitutes "substantially ungelatinized". Therefore, one would not know what the metes and bounds of the claims are.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-14 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borkan et al (US 4,935,243) in view of Tanner et al (6,340,473 B1), Hutchinson et al (US 5,817,323), and Stroud (5,554,385).

Applicant claims are drawn to an edible, chewable, soft gelatin capsule comprising gelatin in about 29%; hydroxypropylated starch in about 11%; glycerol in about 33 %; and water in about 27%; and capsule having a film thickness not exceeding 0.030 inches.

Borkan et al. teach a chewable, edible soft gelatin capsule which comprises a shell comprising about 20-45% gelatin; about 17.5-35% plasticizer (which would read on glycerol); about 15-30% water and about 5-25% of a hydrogenated starch hydrolysate effective to render said shell dispersible and soluble in the mouth of the user (see abstract and col. 2, lines 51-58). The gelatin include fish gelatin (type A) and bovine gelatin (type B) to obtain a gelatin with the requisite viscosity and bloom strength range from 6-300 (see col. 3 lines 30-45). The plasticizer includes glycerin, sorbitol or similar low molecular weight polyols (col.3, lines 48-56). Additional disclosure includes that the soft gel capsules are particularly effective for administration of medicines or other biologically-active substances to persons in medical distress, to elderly, to children, all of whom may not be able to swallow a hard capsule or chew a soft capsule for prolonged period. And this soft gelatin capsules allow these users to easily chew and ingest the active ingredients within the capsules in a palatable form.

Borkan does not especially teach modified starch such as hydroxypropylated starch, plasticizer such as sorbitol, fructose and capsule having a film thickness not exceeding 0.030 inches.

Tanner teaches compositions for the manufacturing of soft capsules comprising modified starch such as hydroxypropylated tapioca starch, hydroxypropylated maize starch and plasticizer such as glycerin and sorbitol (abstract and col. 6, lines 28-45). And capsules made using the rotary die process having shell thickness varying from about 0.024 to 0.1778 cm, which would read on 0.0196 to 0.030 inches (col. 13 lines 18-24).

Hutchinson teaches a soft gelatin capsule shell composition comprising gelatin, water, plasticizer such as glycerol, xylitol, sorbitol, polyglycerol, glucose, fructose, glucose syrup or combination thereof (abstract and col.2 lines 17-25).

Stroud teaches a soft gelatin capsule made by the rotary-die encapusulation process comprising gelatin, glycerol and modified starch. And gelatin capsules have wall thickness of about 0.030 inches (abstract and col. 3 lines 42-46).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate modified starch such as hydroxypropylated starch, plasticizer such as sorbitol or fructose into the soft gel capsules of Borkan. The person of ordinary skill in the art would have be motivated to make these modifications, because Borkan teaches that that the soft gel capsules are particularly effective for administration of medicines or other biologically-active substances to persons in medical distress, to elderly, to children, all of whom may not be able to swallow a hard

capsule or chew a soft capsule for prolonged period. And this soft gelatin capsules allow these users to easily chew and ingest the active ingredients within the capsules in a palatable form. Additionally, capsules made using the rotary die process having shell thickness varying from about 0.024 to 0.1778 cm, which would read on 0.0196 to 0.030 inches would have integrity to enclose desired material for an enhanced period of time, without dissolution or leakage, while still being readily soluble upon consumption. The person of ordinary skill in the art would have a reasonable expectation of success because Borkan and cited references teach composition comprising soft gelatin capsule that are used in the same field of endeavor such as soft gelatin capsules used for oral drug delivery systems, in food products and food additives.

The references do not specifically teach adding the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as gelatin is a combination of fish and bovine gelatin and plasticizer such as fructose for successful encapsulation of products having an appreciable level of water and also to improve softness and flexibility of gelatin capsule, etc. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Response to Arguments

Applicant arguments filed on 01/21/2009 have been fully considered but they are not persuasive.

Applicant argues that Borkan does not teach or suggest the inclusion of starch or other water retentive agent in an ungelatinized or crystalline form.

In response to applicant's arguments against references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 10911 231 USPQ 375 (Fed. Cir. 1986). The Borkan reference was relied upon merely to show that some of the claimed excipients such as gelatin, combination of gelatin, plasticizer such as glycerol were well known in the art at the time the instant application was filed. Further, Borkan, clearly teaches that the presence of hydrogenated starch hydrolysate in required amounts augments the chewable and palatable properties of the shell, as well as assists in its rapid dissolution upon chewing. Applicant argues that Borkan fails to disclose or suggest the thickness of the capsule film and there is no teaching or suggestion that bloom strength may relate to thickness of the capsule film. This argument is not persuasive because Borkan reference is not an anticipatory rejection and is relied based on combinations of references. And Borkan teaches that the gelatin capsule comprises fish gelatin (type A) and bovine gelatin (type B) to obtain a gelatin with the requisite viscosity and bloom strength range from 6-300 (see col. 3 lines 30-45).

Applicant argues that Tanner reference does not teach the use of gelatin and this reference teaches away from the present invention.

This argument is not persuasive since this reference is relied upon to show that it is known in the art to use modified starch selected from modified corn starch (hydroxypropylated corn starch and hydroxypropylated acid modified tapioca starch) capable of forming films from which soft capsule shells can be made. And Tanner teaches that soft shell capsules made by rotary die process is the ability of the compositions to be cast to form film that are mechanically strong and exhibit elasticity sufficient to allow the film to stretch during filling. In other words, the inventive films have dimensional stability, elasticity and strength adequate for use in a continuous commercial process. And Tanner also teaches that it is well know in the art for manufacturing, traditionally, both soft and hard shell capsules using mammalian gelatin as the material of choice of for producing the capsule envelop.

Conclusion

1. No claims are allowed at this time.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr